K082247

OCT 0 8 2008

FDA 510K Summary of Safety and Effectiveness for
EVIS MD PLATINUM RED LIGHT THERAPY

1. General Information

Submitter:

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Contact Person:

C/O Jill Creasy
Aesthetica-Tech
675 Pine Street
Elgin, IL 60123
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Summary Preparation Date: August 6, 2008

2. Device Name

Device Name: **Evis MD Platinum Red Light Therapy**

Classification Name: Laser Surgical instrument for use in General, Plastic Surgery and in Dermatology

Although this device is not a laser, the specifications developer feels this is the closest applicable classification name.

Regulation Number	21 CFR 878.4810
Regulatory Class	II
Product Code	GEX

3. Predicate Device

The Evis MD Platinum Light Therapy device is substantially equivalent to the Omnilux Revive (K030426),

4. Device Description

The Evis MD Platinum Red Light Therapy device that utilizes Light Emitting Diodes to provide LED light to the body. The hand held device contains the power supplies and a built in audible indicator with auto shut off. The device delivers the light to the skin as it moves over the skin. The wavelength for red is 630 +/- 5 nanometer. Evis MD Platinum Red does not use any software.

5. Intended Use and Indications:

The **Evis MD Platinum Red Light Therapy** is intended to provide light to the body.

Generally indicated for dermatology use for the treatment of superficial, benign vascular and pigmented lesions "such as but not limited to solar lentigines, sun spots, liver spots and age spots".

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6. **Comparison of Technological Differences:**
The intended use and technological characteristics of the Evis MD Platinum Red system is virtually identical to the intended use and technological characteristics of the listed equivalent device. Any differences between the Evis MD Platinum Red and the equivalent device have no significant influence on safety or effectiveness of the Evis product.

7. **Nonclinical Performance Data**
The Evis MD Platinum Red was tested and complies with Electrical Safety and EMC testing, which include the requirements of IEC/EN/UL 60601-1 "Medical Electrical Equipment Part 1 – General Requirements for Safety" and was tested in accordance to Medical Directive 93/42/EEC - CSA 601.1, EMC Directive 2004/108/EC IEC/EN 60601-1-2 "Medical Electrical Equipment Part 1-2, General Requirements for Safety – Collateral Standard Electromagnetic Compatibility Requirements and Tests. FCC 47CRF PT 18 Industrial, Scientific, and Medical Equipment. ICES 005 Radio Frequency Light Device

8. **Conclusions**

Based upon an analysis of the overall performance characteristics for the **Evis MD Platinum Red Light Therapy**, Ageless Beauty Corporation believes that no significant differences exist between this system and the predicate systems quoted, therefore, the **Evis MD Platinum Red Light Therapy** device does not impose any new safety or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Ageless Beauty Corporation
% Aesthetica-Tech
Ms. Jill Creasy
675 Pine Street
Elgin, Illinois 60123

Re: K082247
Trade/Device Name: Evis MD Platinum Red Light Therapy
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 19, 2008
Received: September 22, 2008

Dear Ms. Creasy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082247

Device Name: Evis MD Platinum Red Light Therapy
Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082247